Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of pre-bronchoscopy administration of intravenous hydrocortisone in patients with chronic obstructive pulmonary disease: A randomized, double blind, placebo controlled trial

Protocol summary

Summary

(1)Objectives;Effects of pre-bronchoscopy administration of intravenous hydrocortisone in patients with chronic obstructive pulmonary disease (2) Design: A double blind, single center, clinical trial design will conduct in 90 patients with COPD. Random assignment of subjects in both intervention and control groups will categorize(blocking). (3) Setting and conduct; 90 patients with COPD that need bronchoscopy, will divide randomly to two groups (intervention and control groups) and after signing permission form ,underwent bronchoscopy (5) Intervention ;Neither physicians, nurses or patients know which patient is located either in intervention or control group. In each of the intervention and control groups,the Fhberoptic Bronchoscopy(FB) will performe and the measurement of PFT , Hemogolobin oxygen saturation, cough score and vital signs will record on a validated self made checklist before and after procedure. In intervention group intravenous hydrocortisone 200 mg in 5 ml, and for the subjects of the control group, the same volume of saline, will administer 2 hours befor FB . finally results will compare between two groups. (6) main outcome measures;primary outcome variables included, PFT, vital signs, Hemoglobin oxygen saturation and cough severity. we do not have secondary variable outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110922566N1**
Registration date: **2015-12-30, 1394/10/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-30, 1394/10/09

Registrant information

Name

Seyed Mehdi Hashemi Bajgani

Name of organization / entity

Kerman University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research,Kerman University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of pre-bronchoscopy administration of intravenous hydrocortisone in patients with chronic obstructive pulmonary disease: A randomized, double blind, placebo controlled trial

Public title

Effects of pre-bronchoscopy administration of

intravenous hydrocortisone in patients with chronic obstructive pulmonary disease

Purpose
Prevention

Inclusion/Exclusion criteria
inclusion criteria; " diagnosed with chronic obstructive pulmonary disease and FEV1/FVC ratio less than 70%" " history of smoking" "the need of bronchoscopy for the diagnostic studies like hemoptysis, tuberculosis or lung mass". exclusion criteria; "diagnosis of asthma,cystic fibrosis" " oral or intravenous corticosteroid therapy or inhaled corticosteroid dose of 600 micrograms or more per day" " therapeutic bronchoscopy" " intubation".

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Jomhouri Islami Blv, Central Organization

City
kerman

Postal code

Approval date
2013-09-23, 1392/07/01

Ethics committee reference number
52/92/ک

Health conditions studied

1

Description of health condition studied
chronic obstructive pulmonary disease

ICD-10 code
J40, J41,

ICD-10 code description
chronic lower respiratory diseases

Primary outcomes

1

Description
vital sign

Timepoint
pre-bronchoscopy and 1 hour after bronchoscopy

Method of measurement
termometer,choronometer,sphygmanometer

2

Description
cough

Timepoint
pre-bronchoscopy and 1 hour after bronchoscopy

Method of measurement
numboring score from 1 to 10

3

Description
spirometery

Timepoint
pre-bronchoscopy and 1 hour after bronchoscopy

Method of measurement
spirometer

4

Description
saturaton of blood oxygen

Timepoint
pre-bronchoscopy and 1 hour after bronchoscopy

Method of measurement
pulseoxymeter

Secondary outcomes

empty

Intervention groups

1

Description
200 mg hydrocortisone diluted in 10 cc iv 2 hour before bronchoscopy

Category
Treatment - Drugs

2

Description
10 cc normal salin iv 2 hour before bronchoscopy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Dr. Seyedmehdi Hashemi
Street address
Imam Highway ,Afzalipour Hospital
City
kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Kerman University of Medical Sciences
Full name of responsible person
DR.Abbas Pardakhti
Street address
Jahad Blv.Vice chancellor for research,Kerman University of Medical Sciences
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kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research,Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty